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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	00-0050	2575

40158 7590 11/17/2005

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/633,573

Applicant(s)

ASFORA, WILSON T.

Examiner

Jennifer J Maynard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12,33-35,37-39 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12,33-35,37-39 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

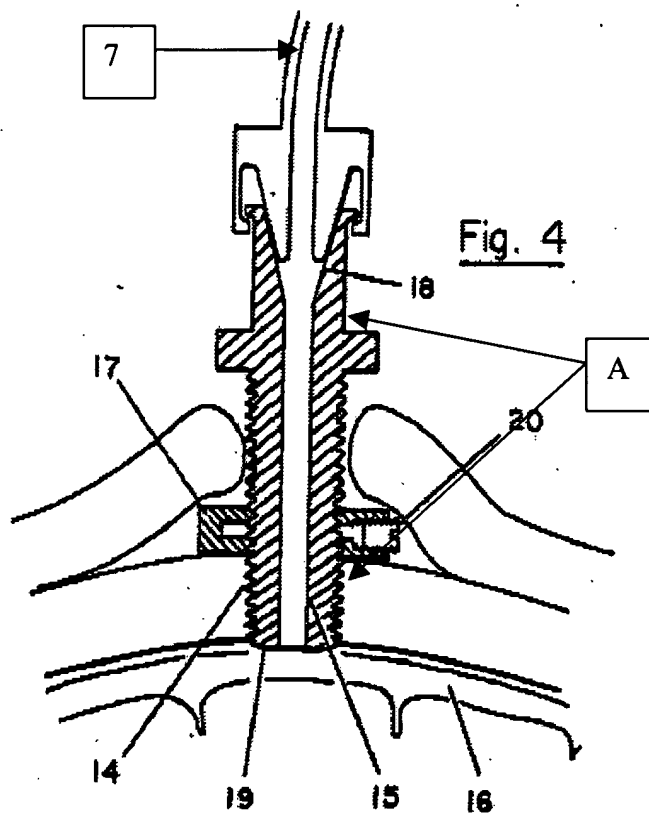
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 33-35, 37-39, 42, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Huppee (US 4,603,890 A).

Swann et al. discloses an adjustable screw comprising a tubular portion (A, see labeled figure below) capable of being inserted into a an opening in a skull of a patient, the tubular portion having a proximal end (19) and a distal end (18) and a lumen (15) extending between the proximal and distal ends, the tubular portion having an exterior surface; a pair of wings (21) for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion; self-tapping threads (14) formed on the proximal end of the tubular portion; a drill bit (32) for forming an opening in the skull of a patient; a stop collar (33) selectively lockable in a position on the drill bit for setting a maximum penetration of the drill bit into a surface; and a conduit (7).

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Swann et al. fails to disclose a retaining means on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion.

Huppee discloses a barbed tubing connector (10) comprising a tubular portion (12) including retaining means (18) on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion.

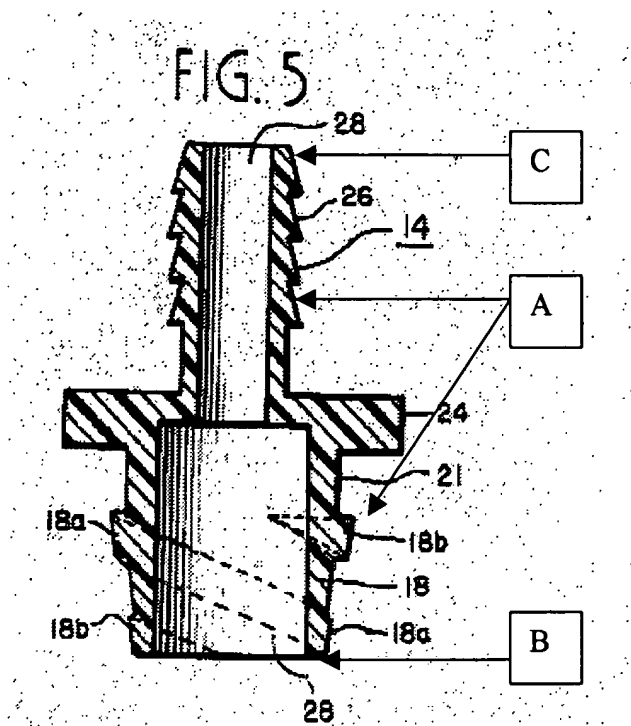
It would have been obvious to one having ordinary skill in the art to have modified Swann et al. with a retaining means as taught by Huppee so as to enable higher operating

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pressures while maintaining a leak free connection without the need for complex connection means on the cooperating end of the flexible conduit.

Claims 1-6, 9, 33-35, 37-39, 42, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akers (US 3,650,551 A) in view of Berg (US 2,373,373 A).

Akers discloses a connector (10) comprising a tubular portion (A, see labeled figure below) capable of being inserted into a an opening in a skull of a patient, the tubular portion having a proximal end (B, see labeled figure below) and a distal end (C, see labeled figure below) and a lumen (28) extending between the proximal and distal ends, the tubular portion having an exterior surface; retaining means (26) on the exterior surface of the tubular portion adjacent to the distal end for engaging an interior surface of a conduit with a flexible wall to releasably retain the conduit on the distal end of the tubular portion; and self-tapping threads (18a, 18b) formed on the proximal end of the tubular portion.



Akers failed to disclose a pair of wings for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion.

Berg discloses a tap comprising a tubular portion (11) including a pair of wings (14, 14') for facilitating finger rotation of the tubular portion, the wings extending outwardly from the tubular portion in substantially opposite directions from the tubular portion.

It would have been obvious to one having ordinary skill in the art to have modified Akers connector with a pair of wings as taught by Berg to provide means for providing torque to the connector so as to aid in manually threading the connector into the opening.

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Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Huppee (US 4,603,890 A), as applied to Claims 1-9, 33-35, 37-39, 42, 44 and 45, above, and further in view of Lake (US 3,766,910 A).

Swann et al. in view of Huppee disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Swann et al. in view of Huppee, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Huppee (US 4,603,890 A), as applied to Claims 1-9, 33-35, 37-39, 42, 44 and 45, above, and further in view of Baudino (US 6,110,155 A).

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Swann et al. in view of Huppee disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. in view of Huppee, by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Huppee (US 4,603,890 A), as applied to Claims 1-9, 33-35, 37-39, 42, 44 and 45, above, and further in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A).

Swann et al. in view of Huppee, and further in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.



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McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. in view of Huppee, and further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swann et al. (US 4,646,752 A) in view of Huppee (US 4,603,890 A), as applied to Claims 1-9, 33-35, 37-39, 42, 44 and 45, above, and further in view Lake (US 3,766,910 A), further in view of Baudino (US 6,110,155 A), and further in view of McNeil et al. (US 4,828,546 A).

Swann et al. in view of Huppee disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference

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numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Swann et al. in view of Huppee, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Swann et al. in view of Huppee, and further in view of Lake disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. in view of Huppee, and further in view of Lake by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

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Swann et al. in view of Huppee, further in view of Lake, and still further in view of Baudino disclose the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Swann et al. in view of Huppee, further in view of Lake and still further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-12, 33-35, 37-39 and 42-45 have been considered but are moot in view of the new ground(s) of rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 571.272.4961. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571.272.4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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